

SECTION 2 - 510(K) SUMMARY
August 2005k052511
page 10 of 1**Name and Address of Applicant**

Nihon Kohden America, Inc.

Attn: Regulatory Affairs

Serrah Namini

90 Icon St.

Foothill Ranch, Ca 92610

(949) 580-1555 Ext 4401

Fax: (949) 580-1550

MAY 24 2006

Trade Name: ECG-1500A series / Cardiofax VCommon Name: Electrocardiograph or ECGClassification Name: The device has been classified as Class II by the Division of Cardiovascular Device Classification Panel under 21 CFR Part 870.2340 "Electrocardiograph" per 74LOS.

Nihon Kohden's ECG-1500A series is intended for medical purposes to process the electrical signals produced by the heart through electrocardiograph electrodes and to produce a visual display, to produce a record and/or to transmit data to a remote computer. The product is a portable ECG acquisition terminal, which measures up to 15 lead ECG waveforms. The measured ECG waveforms are analyzed and a patient record is prepared for transfer to an ECG data filing system thru a wireless LAN or may be printed by integral printer with optional model available with recorder. Measurements and waveforms and diagnostic information are offered to physicians on an advisory basis.

The ECG-1500A series prepares a full page file with 3 to 15 channel selectable formats, waveform display and waveform analyses with measurements. The device includes keyboard data entry, battery with internal battery recharging circuit and AC power operation, all of which are features of the predicate devices. The new device offers an optional PC memory card, comparable to the predicate Nihon Kohden's ECGs. The new device does offer an external optional printer and uses a different type of battery. These changes have been made to address user preferences and do not affect the indication for use or safety and efficacy of the new device.

The device complies with the IEC 60601-1 standard and sub-clause 56.3(c) implemented by 21 CFR Part 868 Performance Standard for Electrode Lead Wires and Patient Cables.

The device was subject to electromagnetic, environmental, safety and performance testing procedures. These tests verified the operation of the device. Software validation tested the operation of the software of the device. The results confirmed that the device performed within specifications.

Therefore based on the above, Nihon Kohden believes that the ECG-1500A series is substantially equivalent to our predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 24 2006

Ms. Serrah Namini
Regulatory Affairs, Associate Director
Nihon Kohden America, Inc.
90 Icon St.
Foothill Ranch, CA 92610

Re: K052511
Trade Name: Cardiofax CE, Model ECG-1500 A
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: April 19, 2006
Received: April 19, 2006

Dear Ms. Namini:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

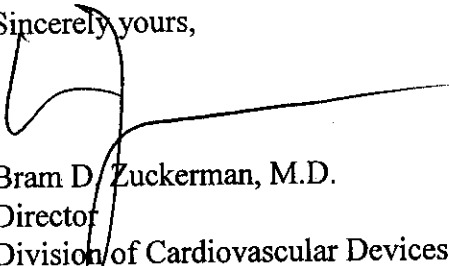
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comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

G. Indications for Use Statement

510(k) Number (if known): k052511Device Name: Cardiofax V; ECG-1500A series

Indications For Use:

The Cardiofax V electrocardiograph is intended for medical purposes to process the electrical signals transmitted through two or more electrocardiograph electrodes to produce a patient record (monitor and recorder) and prepare a record and/or provide wireless transmission of data to a remote printer and/or computer.

For non-interpretive applications, the device is intended for use with a full range of patient populations as determined by a clinician.


The devices also provide an interpretive ECG program intended for use with patients age 3 years and older. The interpretation program is intended to provide an assessment of ECG waveform rhythm and morphology to assist the physician in diagnosis. Assessments provided by the interpretation program are not intended as the sole basis for diagnosis. All assessments provided by the interpretation program are recommended for review by qualified physicians trained in electrocardiography.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)


(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number k052511